Message

From: Newhouse, Kathleen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5F019C8179304045ACD61BC05B571FB0-NEWHOUSE, KATHLEEN]

Sent: 11/6/2014 3:59:51 PM

To: Strong, Jamie [Strong.Jamie@epa.gov]

Subject: RE: Summary of TEB activities

Thank Jamie. Seems like perfect timing since today is my first day back from vacation and this week is the first official week of my detail. I can review this list as I play catch up with my email.

-K

From: Strong, Jamie

Sent: Thursday, November 06, 2014 5:59 AM

To: Newhouse, Kathleen

Subject: Summary of TEB activities

Importance: High

Kathleen,

Here is a list of what is happening on the TEB...hope this helps get you acclimated. We can talk about where you can jump in at our next meeting. Sorry it took me so long to get to writing this up for you!

Jamie

GENERAL DUTIES

Branch Chief

- Review and clear all assessments and related products from TEB
- Maintain assessment schedules to meet deliverables
- 3. Ad hoc review (i.e., I regularly get tasked with review of other division lead IRIS assessments)
- 4. Participate in IRIS management council
- Management liaison to repro/developmental disciplinary workgroup
- 6. Performance appraisals
- Performance and personnel issues
- 8. Mentoring of staff

Acting Associate for Chemical Assessment (Kathleen Newhouse)

- 1. Assist Branch Chief in managing the development of assessments by scientists within the Toxic Effects Branch
- a. Review draft literature search and evidence tables, syntheses, and dose-response analyses
- b. Provide guidance/assistance to TEB scientists as they develop the assessments and proceed through the various review stages
- c. Work with the TEB scientists as they address the issues specific to their assessment and deliver a product to the Branch Chief that is ready for review and reflects the viewpoints of both the scientist and Branch and Division management
- 2. Serve as a mentor to the TEB scientists as they work towards career development, through workgroup participation, publications, and scientific development.
- Additional activities
- a. Co-chair of the GTCI workgroup (need to discuss with Gina and Vince again)
- b. BaP AM
- c. HBCD co-AM

TEB-LEAD IRIS ASSESSMENTS

1. Benzo[a]pyrene (BaP)-Kathleen Newhouse(AM)

- a. Team includes: Karen Hogan, Glinda Cooper, Catherine Gibbons, Linda Phillips, Andrew Kraft (ad hoc basis)
- b. Current status: released for SAB review on 9/25/14; SAB teleconference and meeting date TBD
- c. Management oversight: Jamie
- d. Highlights/Issues-mutagenic mode of action and application of ADAFs; derivation of the first ever dermal slope factor for IRIS; developmental endpoints used as critical effects for RfD and RfC; use of forestomach tumors in cancer risk estimates; WOE descriptor of known human carcinogen based on human mixtures studies, multiple animal studies, and mechanistic data (first for IRIS); used as an example for NRC evaluation of IRIS Program/Process
- 2. Dibutyl Phthalate (DBP)-Xabier Arzuaga (AM)
- a. Team includes: Xabier consults with phthalate workgroup (although they are not meeting with any frequency lately)
- b. Current status: went to Agency Review in 2012 (old template); development of the preliminary package for literature search and evidence tables for release in early 2015
- c. Management oversight: Jamie
- d. Highlights/Issues-staffing (Xabier repeatedly gets pulled off to work on other assignments i.e., repro/dev workgroup) and database size (what data to present in evidence tables and decisions related to cuts based on dose or other) are major issues; human relevance (xenograft studies)
- 3. Diethyl Phthalate (DEP)-James (Andre) Weaver (AM)
- a. Team includes: Todd Blessinger (stats), Glinda Cooper (epi)
- b. Current status: We have a complete draft, but it was never submitted to Agency Review (pre-enhancements) because the CM left for FDA in November 2012; literature search and evidence table package was released in December 2013 and discussed at the February 2013 bimonthly meeting; package/charge for DWGs submitted to IRIS management in June 2014 for distribution (has not gone out to date)
- c. Management oversight: Martin was the primary on this one
- d. Highlights/Issues-consistency of database (the majority of studies do not indicate that DEP induces male repro effects, but recent studies by Pereira report effects in adult male rats at low doses); does not produce phthalate syndrome effects; human studies produce a much lower RfD compared to animal studies
- 4. Diisononyl Phthalate (DINP)-Tenielle Walker (AM)
- a. Team includes: Tenielle consults with phthalate workgroup (although they are not meeting with any frequency lately)
- b. Current status: preliminary package of literature search and evidence tables released in August and discussed at the October IRIS bimonthly meeting; a complete draft exists but needs extensive revision
- c. Management oversight: Jamie
- d. Highlights/Issues-MOA (alpha 2u, PPAR); MNCLs; human relevance (xenograft studies); BMR selection for repro/devel endpoints; potency compared to other phthalates (i.e., is DINP a repro/devel toxicant?); toxicokinetic/route of exposure; adversity of liver endpoints
- 5. Butyl Benzyl Phthalate (BBP)-Tenielle Walker and Andrew Hotchkiss (co-AMs)
- a. Team includes: Tenielle and Andrew consult with phthalate workgroup (although they are not meeting with any frequency lately)
- b. Current status: preliminary package of literature search and evidence tables released in September for discussion at the December IRIS bimonthly meeting; a complete draft exists (so I have been told) but needs extensive revision (again second hand information from Xabier, he says that some text exists but its more like a detailed outline of sorts)
- c. Management oversight: Jamie (Tenielle) and Weihsueh (Andrew)
- d. Highlights/Issues- MNCLs; human relevance (xenograft studies); BMR selection for repro/devel endpoints
- 6. Acrylonitrile (AN)-Jason Fritz and April Luke (co-AMs)
- a. Team includes: Leonid Kopilev (stats), Glinda Cooper (epi), Amanda Persad (epi), Paul Schlosser (PBPK), Karen Hogan (ADAFs)

- b. Current status: AN was released in 2011 for public comment; Extensive comments were received and discussed at the listening session; draft is currently being revised/drafted by DWGs (many haven't started work given the open ended due date provided); plan is to loop back to Agency and Interagency review steps (like BaP) then release for public comment again
- c. Management oversight: Jamie (Jason) and Sue (April); Martin and Ravi used to sit in on weekly AM meetings, but we haven't been having these given the lack of change in status
- d. Highlights/Issues-human cancer data limitations (follow up of a human cancer study is currently ongoing at NCI); MOA (including mutagenicity); chemical specific info for ADAFs; PBPK modeling
- 7. Hexabromocyclododecane (HBCD)-Kathleen Newhouse and April Luke (co-AMs)
- a. Team includes: Alan Sasso (stats)
- b. Current status: We have pieces of synthesis from the DWGs that need to be incorporated and potentially need work; need to develop dose-response section
- c. Management oversight: Jamie (Kathleen) and Sue (April)
- d. Highlights/Issues: sensitive neurodevelopmental study by the same investigators who published papers on PBDEs (using a controversial study design); biological significance of thyroid hormone changes; study quality evaluation for neuro is different than other sections
- 8. Uranium-Xabier Arzuaga (AM)
- a. Team includes: Christine Cai (stats)
- b. Current status: evidence tables have been created; needs an updated literature search (that undergoes a systematic review) and evidence tables need to be updated; old pieces of synthesis exist, but probably need an update and overhaul; modeling on multiple endpoints complete; uranium is in the top 20 needs in the multi-year plan exercise with several offices requesting the assessment; scoping and problem formulation are the next steps
- c. Management oversight: Martin
- d. Highlights/Issues-RfD at or near background; issue of whether to assess both soluble and insoluble forms; developmental toxicity
- 9. PAH Mixtures
- a. Team includes: currently Margaret Pratt and Karen Hogan
- b. Current status: revising draft per SAB comments; will undergo additional peer review (its not clear if we would go back to the panel or to SAB CAAC or use another vehicle)
- c. Management oversight: Martin
- d. Highlights/Issues: Karen is developing list of to do's and issues; staffing/support is lacking
- 10. Hexachlorobutadiene (HCBD)-previously Hui-Min Yang (AM)04
- a. Team includes: Todd Blessinger, Jason Fritz (consult on MOA)
- b. Current status: draft preliminary package of literature search and evidence tables was completed January 2014 (would need an update)
- c. Management oversight: Jamie and Martin
- d. Highlights/Issues-during the scoping meeting no regions or programs indicated this was a priority; MOA for kidney effects and cancer

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